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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,450	12/23/2005	Hisashi Narimatsu	GRT/159-90	6812

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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,450	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,25,27-31,35 and 37-48* is/are pending in the application.

4a) Of the above claim(s) *31,35,37-40 and 45-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,25,27-30 and 41-44* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *SEQ ALIGN*.

Application Status

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/07 has been entered.

In response to the Final Office Action mailed on 05/11/2007, applicants' filed an RCE received on 11/13/07 is acknowledged. Said RCE amended claims 21, 25, 28, 29, canceled claims 22-24, 26 and 36 and added new claims 41-48. Claims 21, 25, 27-31, 35 and 37-48 are pending in the instant Office Action. Claims 31, 35, 37-40 and new claims 45-48 remain withdrawn as they are drawn to non-elected inventions, thus claims 21, 25, 27-30 and 41-44 are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/13/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, examiner is considering the information disclosure statement.

Withdrawn- Claim Rejections 35 USC § 112

Previous rejections of claims 21, 25 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, for enablement is withdrawn due to amendments to the claims.

New-Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 25, 27-30 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) or UniProt # Q8BG28 (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690), in view of Treloar et al., (J. Biol., Chem., 1974, Vol. 249(20): 6628-6632), Iida et al., (FEBS letters, 1999, Vol. 449: 23-234) and Wojczyk et al., (Mol. Biochem. Parasitol., 2003, Vol. 131: 93-107). Claims 21, 25, 27-30 and 41-44 are directed to an enzyme solution comprising an isolated β1,3-N-acetyl-D-galactosamine transferase polypeptide having specific activity and biochemical characteristics and (i) comprising an amino acid sequence of SEQ ID NO: 2 or the amino acid residues 189 to 500 of SEQ ID NO: 2 and (ii) SEQ ID NO: 4 or the amino acid residues 35 to 504 of SEQ ID NO: 4 and encoded by a nucleotide sequence that can hybridize under defined high stringent conditions to the complement of SEQ ID NO: 1 comprising nucleotide residues 106-1503 or SEQ ID NO: 3 comprising nucleotide residues 103-1512. UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and

nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) (*supra*) teach the isolation of a polypeptide (B3 GALNT2; ORF Name= RP4-534P7.1-001) encoding an open reading frame that has 100% sequence homology to SEQ ID NO: 2 or to a polypeptide having an amino acid sequence covering amino acids 189 to 500 of SEQ ID NO: 2 and 100% sequence homology to the encoding polynucleotide of SEQ ID NO: 1 of the instant application, furthermore SEQ ID NO: 2 has 88% sequence homology to SEEQ ID NO: 4 of the instant application that belongs to Glycosyltransferase 31 family members having β1,3-N-acetyl-D-galactosamine transferase activity EC 2.4.1.- (see the following information on SEQ ID NO: 4). UniProt # Q8BG28 annotated as Glycosyltransferase 31 family (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690; Glycosyltransferase 31 family members have β1,3-N-acetyl-D-galactosamine transferase activity EC 2.4.1.-, see http:www.cazy.org/fam/GT31) that has 100% sequence homology to SEQ ID NO: 4 or to a polypeptide having an amino acid sequence covering amino acids 35 to 504 of SEQ ID NO: 4 and 100% sequence homology to the encoding polynucleotide of SEQ ID NO: 3 of the instant application (see enclosed sequence alignment). Both the cited references are silent regarding pH and divalent cation requirement for the specific activity of isolated polypeptides.

1) Treloar et al., teach the optimal conditions for the activity of galactosyltransferase enzymes transferring N-acetyl-D-galactosamine towards N-acetylglucosamine wherein the reaction was carried out in 5 uM of MES buffer pH 5.7 in the presence of 3 uM $MnCl_2$ (pages 6628-6629, Materials and Methods section).

2) Iida et al., teach the isolation, expression and biochemical characterization of three members of human N-acetylgalactosaminyltransferase, optimal pH range and requirement of divalent cations like Mn^{2+} for the activity of said enzymes. Note Iida et al., assayed all three human N-acetylgalactosaminyltransferases in a buffer comprising 20 mM HEPES and 5mM $MnCl_2$ at pH 7.5 (page 230, column 2, section 2.3).

3) Wojczyk et al., teach the isolation, expression and biochemical characterization of a polypeptide having N-acetylgalactosaminyltransferase activity, optimal pH range and requirement of divalent cations of said enzyme. Note Wojczyk et al., assayed said N-acetylgalactosaminyltransferase in a buffer comprising 0.1 M sodium cacodylate at pH 5.5-6.5 and 10 mM concentrations of divalent cations such as Co^{2+}, Mn^{2+} or Mg^{2+} (page 98, column 1, paragraph 3).

Therefore, it would have been obvious to a person of ordinary skill in the art to combine the teachings of UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) or UniProt # Q8BG28 (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690), Treloar et al., Iida et al., and Wojczyk et al., to express the cDNA encoding the polypeptides as taught by UniProt # Q8NCR0 or UniProt # Q8BG28 and to reconstitute the expressed polypeptides in a buffer system as disclosed by Treloar et al., Iida et al., and Wojczyk et al., for the assay of the enzymatic activity of N-acetylgalactosaminyltransferases enzymes, as said buffer conditions are determined to be the optimal pH range and divalent cation requirement. Motivation to combine the teachings derives from the fact β1,3-N-acetyl-D-

galactosamine transferases are employed in industrial applications for their ability to synthesize various sugar molecules and modification of proteins or sugars by their ability to transfer sugar moieties on acceptor sites of said peptide or sugar chain acceptors. The expectation of success is high, because, the disclosure of UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) or UniProt # Q8BG28 (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690) and cloning of genes encoding a polypeptide annotated as Glycosyltransferase 31 family members known to have β1,3-N-acetyl-D-galactosamine transferase activity EC 2.4.1.-, see http:www.cazy.org/fam/GT31) and the teachings of Treloar et al., Iida et al., and Wojczyk et al., disclosing the suitable expression vectors and determination of optimal activity and stability conditions for the isolated polypeptides.

Therefore, claims 21, 25, 27-30 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) or UniProt # Q8BG28 (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690), in view of Treloar et al., (J. Biol., Chem., 1974, Vol. 249(20): 6628-6632), Iida et al., (FEBS letters, 1999, Vol. 449: 23-234) and Wojczyk et al., (Mol. Biochem. Parasitol., 2003, Vol. 131: 93-107).

In support of their request that the prior rejection of claims 21, 25, 27, 29, 30 and 41-44 under 35 U.S.C. 103(a) be withdrawn, applicants' provide the following arguments. These arguments are relevant to the new rejection explained above.

(A) At the time of the claimed invention, applicants' specification determined the buffer and pH conditions for an enzyme to act... applicants' enzyme transfers a sugar to a sugar chain as an acceptor substrate.

(B) Glycosylation enzymes are almost annotated with galactosyltransferase in the art...surprisingly applicants' found that the enzyme of the present invention has transferase activity of N-acetylgalactosamine.

These arguments are not found to be persuasive for the following reasons.

(A) and (B) Reply: Contrary to applicants' arguments, optimal buffer conditions such as MES, HEPES and Cacodylate buffer, pH range and cation requirements for optimal activity and use of said buffers for the activity of N-acetylgalactosaminyltransferases enzymes were well known in the art as noted in the cited references for rejections. Applicants' claims as written do not cite the limitation that the enzyme transfers a sugar to a sugar chain as an acceptor substrate. Furthermore, claims as written are directed to a product and not to a process or a method:

MPEP Chapter 2100-Patentability, clearly states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.<

See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103".

III. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1971). However, the fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (In this case, the examiner had made a rejection under 35 U.S.C. 102(b) over a publication, which disclosed the claimed compound, in combination with two patents teaching a general process of making the particular class of compounds. The applicant submitted an affidavit stating that the authors of the publication had not actually synthesized the compound. The court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. MPEP 2121.02 [R-3].

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

Claims 21, 25, 27-30 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over UniProt # Q8NCR0 (sequence updated 11/09/2001 BC016974 with coding sequence and nucleotide sequence published by Strausberg et al., PNAS., 2002, Vol. 99 (26): 16899-16903) or UniProt # Q8BG28 (sequence updated 12/05/2002 AK035259 annotated as Glycosyltransferase 31 family and nucleotide sequence published by Kawai et al., Nature, 2001, Vol. 409: 685-690), in view of Treloar et al., (J. Biol., Chem., 1974, Vol. 249(20): 6628-6632),

Iida et al., (FEBS letters, 1999, Vol. 449: 23-234) and Wojczyk et al., (Mol. Biochem. Parasitol., 2003, Vol. 131: 93-107).

Conclusion

None of the claims are allowable. Claims 21, 25, 27-30 and 41-44 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on M-F; 8:00-4:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.

Patent Examiner
Art Unit 1652
Dec. 14, 2007.

/Rebecca Prouty/
Primary Examiner
Art Unit 1652